WE CLAIM :

1. A water dispersible tablet formulation comprising an active ingredient as beta lactam antibiotic and optionally a beta lactamase inhibitor, a disintegrating agent, said disintegrating agent being used both intragranularly and extragranularly, and pharmaceutically accepted excipients.

2. The formulation of claim 1 wherein said β-lactam antibiotic is selected from the group consisting of penicillin, cephalosporin and carbapenam.

3. The formulation of claim 1 wherein said penicillin is amoxicillin, said cephalosporins is cefuroxime axetil, cefpodoxime proxetil or cefalexin and said carbapenam is loracarbef or imipenem.

4. The formulation of claim 1 comprising the disintegrant selected from the group consisting of croscarmellose sodium, polyvinylpyrolidone and sodium starch glycolate.

5. The formulation of claim 1 or 4 comprising about 1 % to about 2.5 % w/w the intragranular disintegrant.

6. The formulation of claim 1 or 4 comprising about 1 % to about 5 % w/w the extragranular disintegrant.

7. The formulation of claim 1 comprising the filler selected from the group consisting of lactose, microcrystalline cellulose and starch.

8. The formulation of claim 1 or 7 comprising 40-70 % w/w of said filler.

9. The formulation of claim 1 comprising the lubricants selected from the group consisting of talc, magnesium stearate, stearic acid and colloidal silicon dioxide.

10. The formulation of claim 1 wherein said dispersible tablet has a disintegration time of less than one minute.

11. The formulation of claim 1 wherein said tablets form suspension after incorporating in water.

12. The formulation of claim 11 wherein said suspension formed completely passes through a 750 μm sieve.

13. The formulation of claim 1 wherein said beta lactamase inhibitor is clavulanic acid or a salt thereof.

14. The formulation of claim 13 wherein the clavulanic acid salt is potassium clavulanate.

15. The formulation of claim 13 or 14 wherein the ratio of amoxicillin to potassium clavulanate is 12:1 to 1:1.

16. The formulation of claim 15 wherein the ratio of amoxicillin to potassium clavulanate is 7:1.

17. The formulation of claim 1 or 11 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d90 less than 600 μm.

18. The formulation of claim 1 or 11 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d90 less than 400 μm.

19. The formulation of claim 1 or 11 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d50 less than 300 μm.

20. A process for the preparation of a dispersible tablet comprising a beta lactam antibiotic, an optional beta lactamase inhibitor and an intragranular disintegrant, said beta lactam antibiotic, an optional beta lactamase inhibitor and said intragranular disintegrant incorporated either in the dry mix or the granulating fluid, are aqueous granulated, dried, mixed with extragranular disintegrant, a filler, a flavour, a lubricating agent, a sweetener and the resulting blend is compressed to tablets.

21. The process of claim 20 comprising 30-50 % w/w amoxicillin.

22. The process of claim 20 or 21 wherein amoxicillin has a particle size of d_{90} less than 150 μm.

23. The process of claim 20 or 21 wherein amoxicillin has a particle size of d_{90} less than 75 μm.

24. The process of claim 20 or 24 comprising about 1 % to about 2.5 % w/w of intragranular disintegrant.

25. The process of claim 20 or 24 comprising about 1 % to about 5 % w/w of extragranular disintegrant.

26. The process of claim 24 or 25 wherein the disintegrant is selected from the group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch glycolate.

27. The process of claim 20 wherein the filler is selected from the group consisting of lactose, microcrystalline cellulose and starch.

28. The process of claim 27 comprising 40-70 % w/w of the filler.

29. The process of claim 20 wherein the lubricant is selected from the group consisting of talc, magnesium stearate, stearic acid and colloidal silicon dioxide.

30. The process of claim 20 wherein said granules are dried to an equilibrium relative humidity of less than at 40% at a bed temperature of not more than 60°C.

31. The process of claim 20 wherein said granules are dried to an equilibrium relative humidity of less than 25% at a bed temperature of not more than 50°C.

32. The process of claim 20 wherein said dispersible tablet has a disintegration time of less than one minute.

33. The process of claim 20 comprising beta lactamase inhibitor as clavulanic acid or a salt thereof and beta lactam antibiotic as amoxicillin.

34. The process of claim 33 wherein the clavulanic acid salt is potassium clavulanate.

35. The process of claim 33 or 34 wherein the ratio of amoxicillin to potassium clavulanate is 12:1 to 1:1.

36. The process of claim 35 wherein the ratio of amoxicillin to potassium clavulanate is 7:1.

37. The process of claim 20 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d90 less than 600 μm.

38. The process of claim 20 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d90 less than 400 μm.

39. The process of claim 20 wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d50 less than 300 μm.

40. A process for the preparation of a water-dispersible tablet formulation, the process comprising aqueous granulation of a β-lactam antibiotic and an intragranular disintegrant, incorporated either in the dry mix or in the granulating fluid; drying the granulated mixture; mixing the dried granules with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating agents; and comprising the resulting blend to form water-dispersible tablets.

41. The process of claim 40, wherein the β-lactam antibiotic is selected from penicillins; cephalosporins; and carbapenems.

42. The process of claim 40, wherein the β-lactam antibiotic is amoxicillin.

43. The process of claim 40, wherein the disintegrant is selected from croscarmellose sodium, polyvinylpyrolidone, and sodium starch glycolate.

44. The process of claim 43, wherein the intragranular disintegrant is croscarmellose sodium.

45. The process of claim 43, wherein the disintegrant is present intragranularly at a concentration of about 1 % to about 2.5 % w/w of the tablet formulation.

46. The process of claim 43, wherein the extragranular disintegrant is croscarmellose sodium.

47. The process of claim 43, wherein the extragranular disintegrant is present at a concentration between about 1 to about 5% w/w of the formulation.

48. The process of claim 40, wherein the filler is selected from lactose, microcrystalline cellulose, and starch.

49. The process of claim 48, wherein the filler is present at a concentration of between about 40 and about 70% w/w.

50. The process of claim 40, wherein the lubricants are selected from talc, magnesium stearate, stearic acid, and colloidal silicon dioxide.

51. The process of claim 40, wherein the dispersible tablet has a disintegration time of less than about one minute.

52. The process of claim 40, wherein the suspension formed upon dispersion can completely pass through a 750 μm sieve.

53. A process for the preparation of a stable amoxicillin dispersible tablet formulation, wherein amoxicillin and intragranular disintegrant, incorporated either in the dry mix or in the granulating fluid; drying the granulated mixture; mixing the dried granules with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating agents; and comprising the resulting blend to form water-dispersible tablets.

54. The process of claim 53, wherein amoxicillin comprises about 30 to about 50 % w/w of the formulation.

55. The process of claim 53, wherein amoxicillin has a particle size of d_{90} less than about 150 μm.

56. The process of claim 53, wherein amoxicillin has a particle size of d_{90} less than about 75 μm.

57. The process of claim 53, wherein the disintegrant is selected from croscarmellose sodium, polyvinylpyrrolidone, and sodium starch glycolate.

58. The process of claim 57, wherein the intragranular disintegrant is croscarmellose sodium.

59. The process of claim 57, wherein the disintegrant is present intragranularly at a concentration of about 1 % to about 2.5 % w/w of the tablet formulation.

60. The process of claim 57, wherein the extragranular disintegrant is croscarmellose sodium.

61. The process of claim 57, wherein the extragranular disintegrant is present at a concentration between about 1 to about 5 % w/w of the formulation.

62. The process of claim 53, wherein the filler is selected from lactose, microcrystalline cellulose, and starch.

63. The process of claim 62, wherein the filler is present at a concentration of between about 40 to about 70 %.

64. The process of claim 53, wherein the lubricants are selected from talc, magnesium stearate, stearic acid, and colloidal silicon dioxide.

65. The process of claim 53, wherein the granules are dried to an equilibrium relative humidity of less than about 40% at a bed temperature of not more than about 60°C.

66. The process of claim 65, wherein the granules are preferably dried to an equilibrium relative humidity of less than about 25% at a bed temperature of not more than about 50°C.

67. The process of claim 53, wherein the dispersible tablet has a disintegration time of less than about one minute.

68. The process of claim 53, wherein the suspension formed upon dispersion can completely pass through a 750 μm sieve.

69. The process of claim 53, wherein the amoxicillin granules may be further mixed with clavulanic acid or a salt thereof.

70. The process of claim 69, wherein the clavulanic acid salt is potassium clavulanate.

71. The process of claim 69, wherein the ratio of amoxicillin to potassium clavulanate is about 12:1 to about 1:1.

72. The process of claim 71, wherein the ratio of amoxicillin to potassium clavulanate is about 7:1.

73. A process for the preparation of a water-dispersible tablet formulation wherein the tablet when dispersed in an aqueous media, has a particle size distribution of d90 less than 600 μm.

74. The process of claim 73, wherein the d90 is less than about 400 μm.

75. The process of claim 73, wherein the d50 is less than about 300 μm.

76. A process for the preparation of a stable, dispersible tablet formulation of amoxicillin, and intragranular disintegrant, incorporated either in the dry mix or in the granulating fluid; drying the granulated mixture; mixing the dried granules with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating agents; and comprising the resulting blend to form water-dispersible tablets, wherein the tablet is bioequivalent to the amoxicillin suspension formulation available commercially under the trade name Amoxil™ as required by the USFDA.